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Optimum Insole Hardness for Attenuating Peak Plantar Pressure Under Simulated Loading Scenarios

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ABSTRACT

To provide optimal cushioning capacity, an in-depth understanding of the biomechanical interactions between the foot and therapeutic insoles is mandatory. The goal of this study was to quantify the hardness of plantar soft tissues (PSTs) and investigate the potential association between the hardness of PSTs and the optimum hardness of insole materials. The authors tested the hardness of PSTs in eight plantar regions by using a durometer to examine 30 cadaveric feet. The effects of hardness and loading magnitude on peak plantar pressure at the heel–insole interface were investigated in simulated weight-bearing tests. Significant effects of insole hardness on the cushioning capacity were observed among different loading conditions ($p<0.01$). No significant association was found between the hardness of individual-specific PSTs and optimum cushioning materials ($p<0.05$). This study provides quantitative data on PST hardness, and this knowledge may be valuable for developing insole materials with similar hardness to the PST in order to achieve optimum pressure relief under the foot.

KEYWORDS

Plantar Soft Tissue, Material Properties, Simulate, Individual-Specific

INTRODUCTION

Plantar soft tissues (PSTs) under the heel and metatarsal head regions of the human foot play a key role in cushioning and shock absorption during walking (Ker et al., 1989; Scott et al., 2007; Yan et al., 2023). The PSTs act as a crucial interface between our body and the ground; its positioning relative to the rest of the body plays a pivotal role in maintaining stability, balance, and efficient gait patterns (Cleland, 2023). However, stiffened PSTs due to aging (Hsu et al., 1998; Kwan et al., 2010; Yan et al., 2023) and/or diabetes (Allan et al., 2022; Brady et al., 2023; Jan et al., 2013; Naemi et al., 2022; Zheng et al., 2000) may impair the cushioning capacity of the tissues, eventually developing

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into heel pain, metatarsalgia, and/or diabetic foot ulcers. Foot pain has consistently been connected to falls, causing various injuries in older adults (Menz & Lord, 1999; Mickle et al., 2010).

The therapeutic insole has been considered one potential tool for reducing the incidence of lower extremity injuries by offloading. Most existing therapeutic insoles have been designed with specialized geometry to fit the shape of the plantar surface and with varying material hardness to provide optimum cushioning properties. An investigation of the interaction between foot and footwear is mandatory if one is to select the optimum material for plantar offloading purposes by changing the material characteristics rather than the insole geometry.

Selection of cushioning materials for therapeutic footwear is mostly determined on the basis of the clinician's experiences (Malki et al., 2023; Mandolini et al., 2017; Telfer et al., 2017). Charlotte Apps and her colleagues conducted comprehensive in vivo tests using an in-shoe plantar pressure system, aiming to meticulously compare the mechanical attributes of two distinct insole designs. They elucidated the material-induced impacts on both plantar pressure distribution and perceived comfort during both standard and weighted treadmill walking sessions. Their exhaustive study revealed that a softer, single-material insole exhibited superior efficacy in mitigating plantar pressure, thereby underscoring its potential benefits (Melia et al., 2021). Exploring the material properties of the PST is critical if we are to improve our understanding of the natural cushioning mechanism of the PST, and producing improved footwear with enhanced intrinsic mechanical property, the material properties of which are based on the PST. This may lead to new treatment options for foot pain, specifically that caused by fat pad atrophy, which is common in older adults (Im Yi et al., 2011; Mickle et al., 2011). One option could be insoles that are matched in stiffness with the PSTs. In order to quantify the material property of the PST for the purpose of developing biomimetic materials for footwear design, previous research endeavors have conducted in vivo tests with a tissue ultrasound palpation system (Kwan et al., 2010; Naemi et al., 2022; Tecse et al., 2023; Zheng et al., 2000) and in vitro tests using material compression testing machines (Grigoriadis et al., 2017; Miller-Young et al., 2002). These studies focused on testing the elastic modulus of PSTs, mostly in the heel region rather than in all plantar regions. However, the methods used and the parameters tested in previous studies are too complicated to be directly applied to footwear design and clinical assessment. Thus, current footwear design is usually performed without taking into consideration the individualized material property of the PSTs.

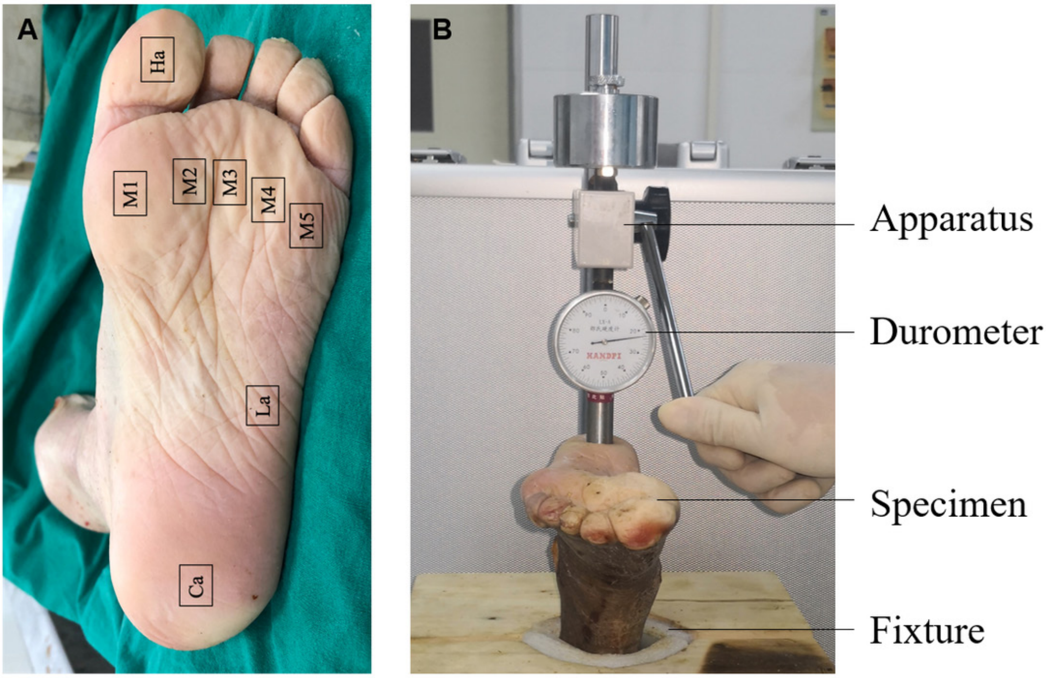
Hardness offers a simple yet useful parameter that directly reflects the stiffness property of the PSTs. Shore hardness, specifically of the Type A variety, is a universally adopted scale within footwear design circles that serves as a reliable metric for assessing the rigidity and durability of shoe materials. Previous studies have indicated that Shore hardness is a valid and reliable measurement for PST biomechanics (Tonna et al., 2024), and we have used a Shore A durometer (Type A) with a customized apparatus to quantify the hardness of PSTs in vitro (Helili et al., 2021). The apparatus was used to hold the durometer so that a standardized hardness test with improved test–retest reliability could be performed.

In this study, we measured the hardness of PSTs in vitro and evaluated the cushioning capacity of the footwear materials, the hardness of which was determined by PST hardness. The main objective was to investigate the potential association between the hardness of individual-specific PSTs and the optimum hardness of cushioning materials.

MATERIALS AND METHODS

Thirty fresh frozen cadaveric feet from 17 nondiabetic donors (ages 61–75 years, 1.12±5.23 years, 11 men, 6 women) were obtained from the Department of Anatomy, Shanghai Medical College, Fudan University. Each foot had been amputated 15 cm above the medial malleolus.

Figure 1. Division of foot (panel a) and measurement of plantar soft tissue hardness in vitro by using the shore a durometer (panel b) by test stand



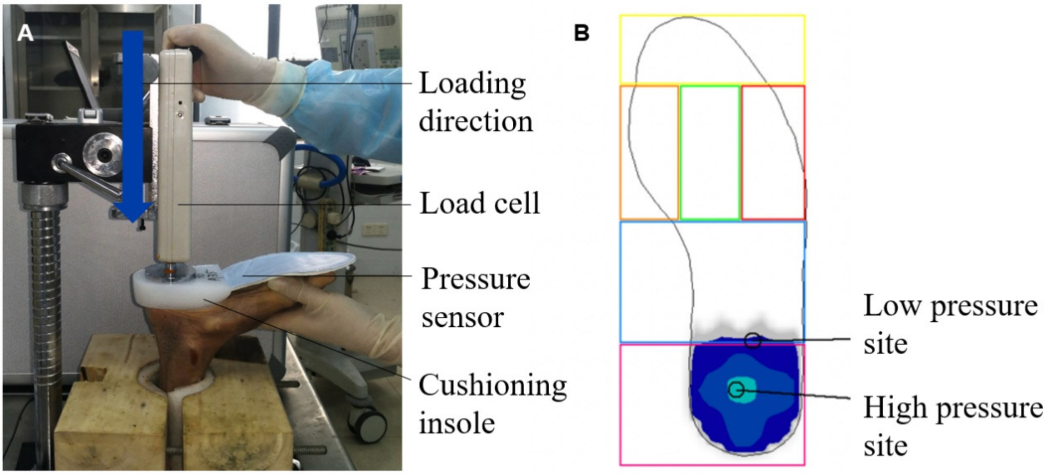
Shore Hardness Measurement

To quantify the hardness of PSTs, we used a Shore A durometer (LX-A, Type A, Yueqing Handpi Instruments Co., Ltd., Zhejiang, China) by test stand. The stand was used to hold the durometer to complete the test, make it accurate and stable, and improve the test–retest reliability. Similar hardness testers have been used to measure the hardness of soft tissues in in vivo studies (Piaggesi et al., 1999; Periyasamy et al., 2012; Yoon et al., 2017). Shore A durometers are designed to measure the hardness of soft rubber, elastomers, leather, wax, and so on. They are widely used in the footwear field to quantify the hardness of insole materials. Before the commencement of the trial, the durometer underwent regular inspections to ensure its precision and accuracy were maintained. Each foot was routinely thawed at room temperature (28°C). During test, each foot was fixed by a wooden stand, and the Shore durometer by test stand was pressed to the surface of the plantar region by keeping the durometer's bottom surface parallel with the plantar surface as shown in Figure 1, Panel b. The number on the dial plate represents the Shore A hardness (HA) of the PST. In addition, the durometer lists the Shore values, which can range from 0 to 100. Soft tissue has a low Shore value, whereas hard tissue has a high Shore value. PSTs that play crucial role in weight-bearing activities beneath the heel, lateral midfoot, first to fifth metatarsal head, and big toe were tested as shown in Figure 1, Panel (a). Each region was tested three times, and the results were averaged to evaluate the hardness of the region.

Evaluation of the Cushioning Capacity of Heel Pads with Varying Hardness

We purchased custom-made silicone heel pads (i.e., insoles) with similar qualitative mechanical characteristics but different sizes and hardness levels (Shore A10, 15, 20, 25, 30, 35) from Ottobock Industries Co., Ltd. (Shanghai, China). The heel pads were retested using a Shore A durometer to confirm the hardness. The effect of material hardness and loading magnitude on the cushioning capacity of the heel pads was investigated in a series of mechanical tests using each foot, as shown

Figure 2. Testing setup for investigating the cushioning capacity of heel pads with varying hardness



Note. Loading tests were applied using a force gauge with a test stand, and the peak pressure between the heel and the heel pad was measured using an in-shoe pressure measurement system (Panels a and b). Panel c: an example of the plantar pressure distribution with simulated Lording test.

in Figure 2. Weight-bearing tests were performed at 250, 300, and 350 N to simulate the ground reaction force under the heel during static standing. Loading was applied using a force gauge by a test stand (HP-500, Yueqing Handpi Instruments Co., Ltd., Zhejiang, China), and the peak pressure between the heel and the heel pad was measured using an in-shoe pressure measurement system (GP MobilData Bluetooth, Go-Tec GmbH, Münster, Germany; Figure 2). The GP MobilData Bluetooth was equipped with 64 resistive-pressure sensors, and the measured data were transmitted at 200 Hz to a laptop via a Bluetooth transmitter to record peak pressure. The loading tests were performed on each foot with six hardness values of heel pads and barefoot, and the corresponding peak pressure was analyzed. The hardness of the silicone heel pads, which minimized the peak pressure and the hardness of PSTs in the heel region, were compared to explore the potential correlation between the hardness of optimum cushioning materials and PSTs.

Data Analysis

Statistical analyses were performed using SPSS (Version 20). Descriptive statistical analyses were conducted using $M \pm SD$. Significant differences in peak pressure between each level of heel pad hardness were analyzed with a one-way analysis of variance. When significant findings were obtained, we made post hoc comparisons, followed by a Bonferroni post hoc analysis, to examine each type difference. The association between the hardness of individual-specific PST and optimum cushioning material was analyzed using Pearson correlation coefficients. The significance level was set at $p < .05$.

RESULTS

The mean hardness (Shore A value) of PSTs in eight regions are presented in Table 1. The heel pads were retested to confirm the hardness of the material. The mean peak pressures between the heel surface and each heel pad hardness, corresponding to three magnitudes of loading on 30 cadaveric feet, are presented in Table 2. The numbers of each heel pad hardness level that minimized the peak

Table 1. Hardness (shore A values) of plantar soft tissues at eight foot regions

Region and hardness (*M*±*SD*)							
Ca	**La**	**M1**	**M2**	**M3**	**M4**	**M5**	**Ha**
19.98±3.83	15.19±2.91	18.69±3.70	18.16±2.43	17.66±2.20	17.00±2.32	17.37±3.19	11.55±2.36

Table 2. Mean peak pressure for different magnitude of loads for all heel pads and barefoot: one-way analysis of variance

Load (N)	*M*±*SD*							*F*	*p*
	Barefoot	SP 1	SP 2	SP 3	SP 4	SP 5	SP 6		
250	84.20±17.88	55.87±9.44	55.07±11.17	56.10±11.98	59.40±14.49	65.47±13.7	71.90±13.92	19.373	.000
300	98.9±22.14	73.8±14.76	70.3±12.84	69.90±16.85	68.20±15.96	72.03±16.49	80.07±18.2	12.019	.000
350	117.8±28.57	85.57±20.89	83.27±20.87	81.23±18.95	80.27±19.28	84.37±20.31	94.77±20.85	11.389	.000

Note. SP = silicone heel pad.

pressure between the heel surface and pad, corresponding to each magnitude of load, are presented in Table 3.

Effects of Material Hardness and Loading on the Cushioning Capacity of the Heel Pad

On the basis of the range (HA13–28, 19.98±3.83) of hardness of PSTs at heel for 30 feet, six types of hardness of silicone heel pads (HA10, 15, 20, 25, 30, 35) were used in this study. Three different magnitudes of loading tests were performed for each foot. The effect of material hardness on the cushioning capacity of heel pads was analyzed using a one-way analysis of variance, and the average peak pressure differences were observed among different conditions ($p < .01$; see Table 2). The Bonferroni post hoc analysis showed that the peak pressures for all 30 feet during different magnitudes of loading tests were higher in the barefoot condition than in the heel pad condition ($p < .01$). When the load was 250 N, the Shore A35 heel pad hardness pad exhibited a higher peak pressure than that of the Shore A25, 20, 15, and 10 heel pad hardnesses ($p < .01$). When the loads were 300 and 350 N, no significant difference existed among the average peak pressures corresponding to each heel pad hardness. However, the average peak pressure for all feet showed that when the load was 250 N, the optimum heel pad hardness that minimized the peak pressure was HA 10–20 (83.3%). When the load was 300 N, the optimum hardness was HA 20, 25 (30.0% and 26.7%, respectively). When the load was 350 N, the optimum heel pad hardness as relatively higher, HA 20, 25 (26.7% and 40.0%, respectively). As the load increased, the material hardness required for optimum cushioning also increased (see Table 3).

Association Between the Hardness of Individual-Specific PSTs and Optimum Cushioning Materials

For each foot, the optimum hardness of the cushioning material was determined by the hardness of the heel pad that minimized the peak pressure. We computed the Pearson correlation coefficients to make comparisons between the hardness of the PSTs (heel region) and the hardness of the optimum cushioning materials. The results showed no significant association between the hardness of individual-specific PSTs and optimum cushioning materials ($p > .05$).

Discussion

Many researchers have focused on the compression properties of PSTs; their findings have been successfully used in finite element modeling to provide new insights into the internal stress of PSTs

Table 3. Frequency of each heel pad based on loads for optimum pressure relief

Load (N)	Barefoot	SP 1	SP 2	SP 3	SP 4	SP 5	SP 6
250	0	9	8	8	5	0	0
300	0	3	5	9	8	4	0
350	0	1	3	8	12	6	0

Note. SP = silicone heel pad.

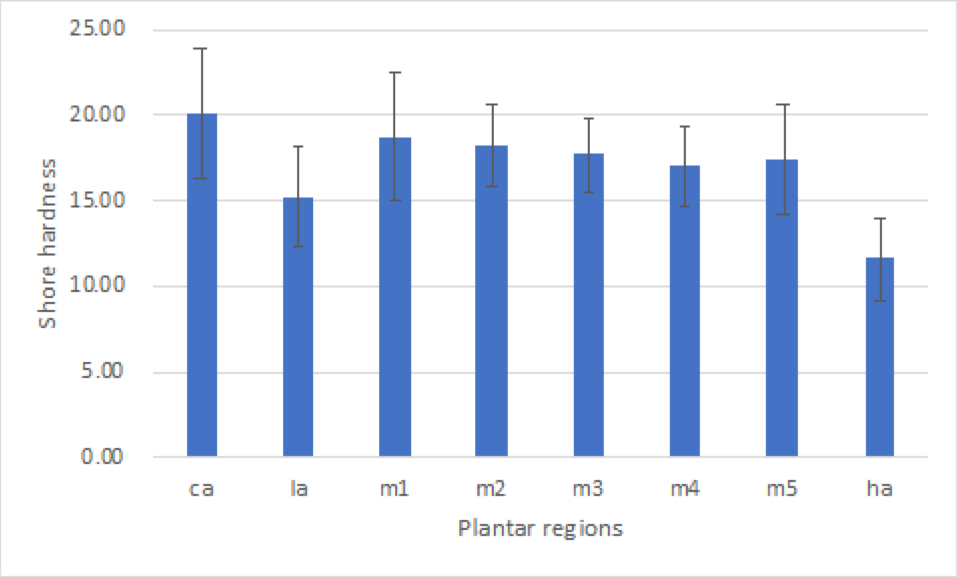
(Chen & Lee, 2015; Fontanella et al., 2013; Isvilanonda et al., 2016). However, the hardness of the regional PSTs has been rarely investigated. For clinical assessment and footwear design, doctors always evaluate the hardness of PSTs by palpation; this method is easily affected by demographic factors. The first objective of this study was to quantify the hardness of PSTs at the heel, lateral midfoot, first to fifth metatarsal head, and big toe regions by using a Shore A durometer. The results showed that the PSTs have region-specific hardness beneath the eight foot regions. The average hardness value of the PST at the heel is higher than that in other regions and is lower at the big toe. At the metatarsal head regions, the first, second, and fifth regions are harder than the third and fourth regions. The lateral midfoot region is softer than the rear foot and metatarsal head areas (Table 1 and Figure 3). At the heel, midfoot, and metatarsal head areas, our results are in agreement with those previously observed (Periyasamy et al., 2012), in which the hardness of PSTs was manually measured in vivo by using a durometer (Type OO); at the big toe, the tissue was found to be harder than other regions in all the test groups, which is in contrast to our results. The difference between our study and the previous study at the big toe may be due to variations in testing methods and/or research objects. To quantify the hardness of the PST, a Shore durometer (Type OO) has been used in in vivo studies (Periyasamy et al., 2012; Piaggesi et al., 1999), whereas tests were manually operated without a test stand, which means the results were affected by demographic factors. In the present study, we used a Shore A durometer by test stand, which can improve the test accuracy and increase the test–retest reliability. The testing method adopted in the present study has been widely used to evaluate the hardness of footwear materials, and the results were readily compared with insole materials.

A previous modeling study indicated that medium heel stiffness is optimum for health-related mechanical responses (Lin et al., 2017), but previous studies have not quantified the optimum heel pad stiffness. We quantified the hardness of PSTs at eight regions using Shore A values, which provide the basic data for clinical assessment and prediction of PST pathologies.

The second objective of this study was to investigate the potential association between the hardness of individual-specific PSTs and optimum cushioning materials by conducting a series of mechanical tests on each foot. The results of the loading tests indicated that the load amount affects the cushioning capacity of heel pads: As the load increases, a relatively harder material is needed for optimum cushioning (Table 3, Figure 4). This finding is consistent with those of a study (Chatzistergos et al., 2017) that investigated the effects of loading on the cushioning ability of BPU materials by conducting in vitro tests with a three-dimensional printed heel model; the results revealed that overweight individuals may need relatively hard materials for optimum cushioning.

Each level of heel pad hardness used in our study significantly reduced the peak pressure under the heel than barefoot condition ($p < .01$). When the load was 250 N, the Shore A35 hardness of the heel pad exhibited a higher peak pressure than the Shore A25, 20, 15, and 10 heel pad hardnesses ($p < .01$), indicating that the hardness of materials can affect the cushioning capacity of heel pads. Previous studies have revealed that footwear and orthoses can reduce the peak pressure, and material hardness can affect the pressure-relieving properties of cushioning footwears (Bonanno et al., 2011; Bousie et al., 2018; Chatzistergos et al., 2017; Hahni et al., 2016; Ibrahim et al., 2013; Mandolini et al., 2017). Our findings also confirmed the cushioning capacity of heel pads. For each foot, comparisons

Figure 3. Average hardness (shore A values) of plantar soft tissues at eight foot regions

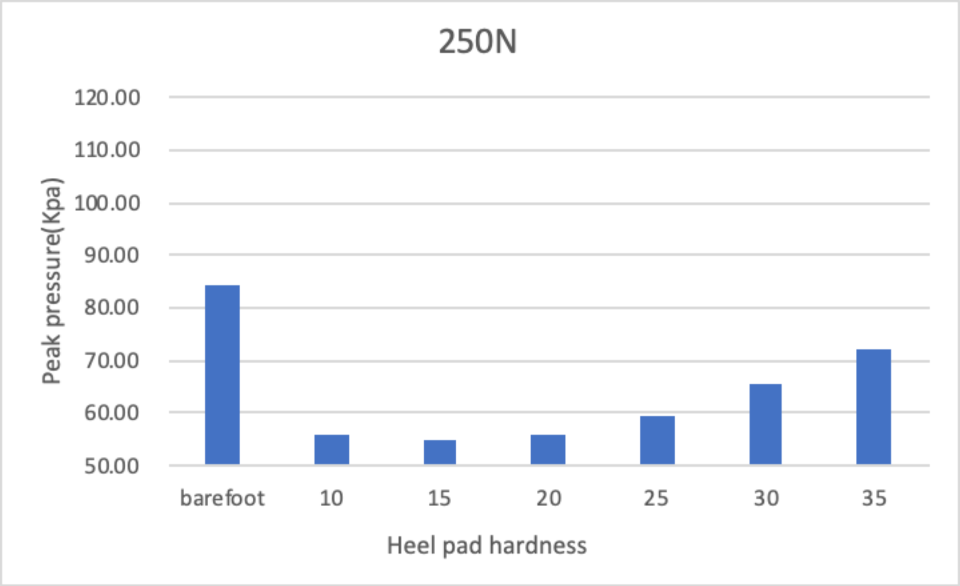


between the hardness of the PST (heel region) and the hardness of the optimum cushioning material revealed no significant associations ($p < .05$). In this investigation, given the technical complexity of loading simulations for total foot regions in vitro, we conducted the loading simulation test only at the heel region and compared the hardness between the PST at the heel and the optimum cushioning of heel pad. The difference between the hardness of heel regions for the 30 feet was insignificant; hardness was mostly approximately 20HA with low dispersion (HA13–28, 19.98±3.83). As a result, the association between the hardness of individual-specific PST and the optimum cushioning material would be difficult to determine only on the basis of heel region. However, after a thorough examination of the test data results, we noted a trend that HA20–25 hardness of heel pads have better cushioning capacity, and the results indicated that HA20–25 hardness of insole materials more effectively reduce peak pressure. Other factors also need to be considered, such as age, gender, weight, comfort and fatigue, and should be examined further in future in vivo research.

In the present study, we quantified the hardness of PSTs at eight foot regions. This study is the first attempt to measure the PST hardness in vitro using a Shore A durometer, which has been widely adopted to evaluate the hardness of footwear materials. Our results provide basic data for the clinical assessment and prediction of PST pathologies and for the selection of insole materials whose hardness is similar to the PSTs, to improve comfort. We also investigated the potential association between the hardness of individual-specific PST and optimum cushioning material at the heel region to set the basis for optimum cushioning material selection for personalized insole design. No significant correlation was observed. Further investigation of total foot regions is necessary to confirm the association between the hardness of individual-specific PST and the optimum cushioning material.

A limitation of this study is that the material behavior of the cadaveric PST might not represent living plantar tissue; also, freezing might have affected the results. Previous studies have demonstrated that cadaveric studies and freezing have little effect on the compressive properties of the plantar fat pad (Bennett & Ker, 1990; Weijers et al., 2005). However, the PST hardness might differ from living tissue, so further work is needed to investigate the influence of cadaveric studies on tissue hardness.

Figure 4. Average peak pressure achieved by each hardness heel pad during three mechanical tests for 30 feet



CONCLUSION

This study provides quantitative data about PST hardness, and this will be helpful in developing materials whose hardness is similar to the PST and thus in achieving optimum pressure relief in the form of natural cushioning of PST to improve comfort. We did not find a significant association between the hardness of individual-specific PST and optimum cushioning material at the heel region, but we did note a trend that HA20–25 hardness levels have better cushioning capacity at the heel region.

CONFLICTS OF INTEREST

We wish to confirm that there are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome.

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